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EXAMINER

GABEL, GAILENE

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/550,276
Filing Date: April 15, 2000
Appellant(s): SPAULDING, GLENN F.

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Coe F. Miles
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This Supplemental Answer is set forth for further consideration and explanation of issues raised and required by the Board of Patent Appeals and Interferences in their decision to remand the application to the examiner on record.

In regards to the status of the substitute specification and abstract which were submitted with the amendment filed on August 12, 2002, Examiner acknowledged

receipt of the substituted specification and abstract which were fully compliant under 37 CFR 1.125. The marked-up copy of the specification and abstract are scanned in IFW under "Applicant Arguments and Remarks" (see pages 15-28) in Applicant's Amendment filed on August 22, 2002. Scanning customer support has been advised to rescan pages 15-28 under a separate heading: Marked-up Substitute Specification and Abstract. Examiner regrets her incomplete statement of acknowledgement on the record of the status of the substituted specification in lacking indication of its entry. Examiner also regrets further confusion in having made continuous reference to "Surmodics, Inc." in the original specification, rather than the substituted specification.

Accordingly and for record purposes, the marked-up copy of Applicant's Substitute Specification and Abstract, filed on August 22, 2002, have been entered. Pages and paragraphs used to reference specific statements provided in the specification have been corrected and updated accordingly, in this Supplemental Examiner's Answer.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 5,582,795 NISHINA et al. 10 December 1996

US 5,352,879 MILCH 04 October 1994

US 5,126,544 IZUMI 30 June 1992

Examiner regrets previous oversight in citing incorrect United States patent number for Izumi et al. (US Patent 5,126,554). The correct patent number for Izumi et al. is US Patent 5,126,544.

US 6,254,834 ANDERSON et al. 3 July 2001

SURMODICS INC., Eden Prairie, MN: Applicant's admitted prior art at page 6, Example 2 of the substitute specification.

Examiner regrets previous oversight in citing incorrect page number in the substitute specification upon which "Surmodics, Inc" is made reference to.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

I. Rejections Withdrawn:

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being vague and indefinite for reciting, "a barcode adapted to be interrogated" is, hereby, withdrawn.

II. The following grounds of rejection are applicable to the appealed claims:

To address the means-plus-function limitations in the claims as required by the Board, a three-prong analysis was made in order to determine as to whether the claim

limitations are interpreted to invoke 35 USC 112, sixth paragraph. In this case, claims 1 and 10 were determined to have failed the third prong of the analysis, which requires that the phrase “means for” or “step for” must not be modified by sufficient structure, material, or acts, for achieving the specified function.

With respect to the third prong of the analysis, even when a claim element uses language that generally falls under the step-plus-function format, however, 112, sixth paragraph still does not apply when the claim limitation itself recites sufficient acts for performing the specified function (*Seal-Flex*, 172 F.3d at 849, 50, USPQ2d at 1234 (*Radar*, J. concurring)). *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531, 41 USPQ2d 1001, 1006 (Fed. Cir. 1996) holding “perforation means … for tearing” does not invoke 35 USC 112, sixth paragraph, because the claim describes sufficient act supporting the tearing function , i.e. perforating. In this case, claims 1 and 10 recite, “rotating means for rotating”, “a detector means for detecting”, “determining means for determining”, “a movement means for moving”. In all aforementioned occurrences, the claim limitations recite sufficient acts for performing the specified function. Accordingly, the claim limitations in claims 1 and 10 which recite “means for” have not been treated under the provisions mandated under 35 USC 112, sixth paragraph.

The scope of the claims as set forth and encompassed in Applicant’s disclosure has been determined as follows:

Claim 1 which recites, *the “rotating means” adapted to receive and rotate a transparent cylinder along a longitudinal axis of the transparent cylinder*, is implicitly

deemed to correspond to a motor means having a shaft disposed to the cylinder (page 5, lines 8-10) or a stepper motor microstepped for vertical rotation (page 5, lines 24-25).

Claim 1 which recites, *the “determining means” for determining at least one cytometric characteristic of a sample disposed in said transparent cylinder based on the light signal*, is implicitly deemed to correspond to biomass analysis process (page 6, lines 28-30), confocal analysis process (page 7, lines 1-9), and different **sensors** which provide multi-parameter measurements such as CCD arrays, light scatter detectors, multicolor detectors, infrared detectors, photon counters, scintillation detectors, radioactivity detectors, confocal microscopy collection optics (see page 9, line 1 to page 10, line 1 and lines 25-30) as they can be used in determining at least one cytometric characteristic of a sample disposed in the transparent cylinder based on the light signal (cell phenotype, cell morphology). Since both the claims and the instant disclosure do not clearly link what specific described structures are intended to encompass the “determining means” recited in claim 1, it is proper for purposes of *prima facie* anticipatory or obviousness rejection to interpret “determining means” for determining at least one characteristic of a sample disposed in said transparent cylinder based on light signal, to implicitly correspond to the “barcode reader” described in page 7, lines 11-15 (Example 7), which barcode readers are sensors which provide parametric measurements based on light signal consonant to those described in Example 15 used in determining at least one cytometric characteristic of a sample disposed in the transparent cylinder based on the light signal; because unpatented claims are given the broadest interpretation consistent with the specification.

Claim 1 which recites, *the “movement means” for moving the transparent cylinder and the light source and detector in a longitudinal axis relative to one another*, is implicitly deemed to correspond to a linear actuator or linear motor means with a shaft or a worm gear assembly (gear means) (page 3, lines 20-25, page 5, lines 13-18 and 23-24, page 7, lines 20-22).

Claim 10 which recites, *the “rotating means for rotating a transparent cylinder about a longitudinal axis of the transparent cylinder*, is implicitly deemed to correspond to a motor means having a shaft disposed to the cylinder (page 5, lines 8-10) or a stepper motor microstepped for vertical rotation (page 5, lines 24-25).

Claim 10 which recites, *the “detector means” for detecting a light signal generated by the light source and reflected from the transparent cylinder while the transparent cylinder is being rotated by the rotating means*, is implicitly deemed to correspond to structures encompassed in the specification as [diode] laser or light source and photodiode or photodetector or photomultiplier tubes (page 1, lines 10-13, page 2, lines 16-19, page 3, lines 20-23, page 4, lines 7-9, page 5, lines 25-28, page 7, lines 27-30).

Claim 10 which recites, *the “determining means” for determining at least one cytometric characteristic of a sample disposed in said transparent cylinder based on the light signal*, is implicitly deemed to correspond to biomass analysis process (page 6, lines 28-30), confocal analysis process (page 7, lines 1-9), and different **sensors** which provide multi-parameter measurements such as CCD arrays, light scatter detectors, multicolor detectors, infrared detectors, photon counters, scintillation detectors,

radioactivity detectors, confocal microscopy collection optics (see page 9, line 1 to page 10, line 1 and lines 25-30) as they can be used in determining at least one cytometric characteristic of a sample disposed in the transparent cylinder based on the light signal (cell phenotype, cell morphology). Since both the claims and the instant disclosure do not clearly link what specific described structures are intended to encompass the “determining means” recited in claim 10, it is proper for purposes of *prima facie* anticipatory or obviousness rejection to interpret “determining means” for determining at least one characteristic of a sample disposed in said transparent cylinder based on light signal, to implicitly correspond to the “barcode reader” described in page 7, lines 11-15 (Example 7), which barcode readers are sensors which provide parametric measurements based on light signal consonant to those described in Example 15 used in determining at least one cytometric characteristic of a sample disposed in the transparent cylinder based on the light signal; because unpatented claims are given the broadest interpretation consistent with the specification.

Claim 10 which recites the *“movement means” for moving the transparent cylinder and the light source and detector means in relative motion*, is implicitly deemed to correspond to a linear actuator or linear motor means with a shaft or a worm gear assembly (gear means) (page 3, lines 20-25, page 5, lines 13-18 and 23-24, page 7, lines 20-22).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A) Claims 1, 2, 10, 11, 21, 22, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishina et al. (US Patent 5,582,795).

Nishina et al. disclose a hold-transfer system or apparatus for use in analyzing fluids such as blood and medicines (see column 1, lines 6-9). The apparatus comprises a rotating means, i.e. a stepper motor, which receives and rotates transparent cylinders (test tubes) about the longitudinal axis of the transparent cylinder. Transparent guards are installed for protection of transparent cylinders. The apparatus has a light source such as laser or light emitting diode (LED) which illuminates a portion of the transparent cylinder while the transparent cylinder is being rotated. The apparatus also includes a movement means (first and second motors, i.e. linear actuator) for moving the transparent cylinder, the light source and barcode reader along a longitudinal axis relative to one another (see column 3). The apparatus further comprises a detector, i.e. photosensor, and determining means (automatic scanning type barcode reader) which detects light signal provided by the light source and reflected from the barcode while the transparent cylinder is being rotated. The barcode reader determines information encompassing cytometric characteristics incorporated into a barcode label, on a sample

disposed in the transparent cylinder (see column 3, line 40 to column 4, lines 19, and column 5, lines 4-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

B) Claims 24, 25, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Milch (US Patent 5,352,879).

Nishina et al. has been discussed supra. Nishina et al. is silent in teaching that a detector comprises an analog to digital converter, a photomultiplier tube, and a processing means.

Milch discloses a detector means that reads light signal from optically encoded information on a barcode label. The detector means comprises an analog to digital converter, a photomultiplier tube (two photodetectors), and processing means (control means or CPU) (see claims 4 and 5 of Milch et al.).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the analog to digital converter, photomultiplier tube, and processing means as taught by Milch into the apparatus as taught by Nishina because

digital converters and photomultiplier tubes appear to constitute obvious variations of detectors routinely known in the art used to detect light signal.

C) Claims 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Izumi (US Patent 5,126,554).

Nishina et al. has been discussed supra. Nishina et al. differ from the instant invention in failing to disclose that the detector comprises a charge-coupled device (CCD).

Izumi discloses a detector means for use in reading light signal reflected from barcode symbols. According to Izumi, the detector comprises a CCD. (See claim 3 of Izumi).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the CCD as taught by Izumi into the apparatus as taught by Nishina because CCDs appear to constitute obvious variations of detectors routinely known in the art used to detect light signal.

D) Claims 3, 13-18, 26-28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Anderson et al. (US 6,254,834).

Nishina et al has been discussed supra. Nishina et al. differ from the instant invention in failing to disclose that the transparent cylinder (which has a closed end and an open end) includes a cell guide member and, has organic photoreceptor and

standards affixed thereon. Nishina et al. further differ in failing to disclose that the apparatus has more than one light source.

Anderson et al. disclose a cytometric apparatus or system for characterizing microorganisms such as bacteria, virus, mycoplasma, or yeast cells in a sample contained in a transparent cylinder (centrifuge tube) (see column 10, lines 22-45). The transparent cylinder has an open end (upper region), a middle cell guide member, and a closed end (lower region) with successively smaller diameters (see columns 4-5). The open end is for receiving a sample which can be plugged with a sealing cap and the lower end is a tubular microbanding region for isopycnically banding all the infectious particles or cells in the presence of a fluorescent dye or a combination of fluorescent dyes. Anderson et al. disclose that the inner surface of the cylinder can be modified by treatment with non-absorptive material (see column 5). Anderson et al. also teach affixing standards into the transparent cylinder (see Example). Anderson et al. provide use of the apparatus in combination with one or more light sources emitting at different wavelengths and detection systems, i.e. diffraction grating (see column 7, lines 32-41 and column 10, lines 8-21 and 46-67). The optical signal detected from the microbanding is processed in a processing means (computer).

It would have been obvious to incorporate a cell guide member having organic photoreceptor and standards affixed thereon as taught by Anderson into the apparatus of Nishina because Nishina specifically taught that the adapters upon which the transparent cylinders are disposed can come in various shapes to accommodate for any change in shape or configuration of a transparent cylinder (see column 6, lines 1-14),

such as for example those that have incorporated thereto, cell guides having successively smaller diameter towards the lower end of the transparent cylinder such as taught by Anderson.

E) Claims 4, 19, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Anderson et al. (US 6,254,834) as applied to claims 13-18, 26-28, and 31 above, and further in view of Surmodics, Inc.

Nishina et al. and Anderson et al. have been discussed supra. Nishina et al. and Anderson et al. differ from the instant invention in failing to disclose dibromo anthranthrone which is an organic photoreceptor material activated by a wavelength of approximately 300 nm to 800 nm.

Applicant, by way of disclosure at page 6, lines 5-10, admits that incorporation of photo cross-linking agents into the inner wall of cylinder surfaces, is known and used commercially by Surmodics, Inc. The specification provides that "The inner wall of the cylinder is modified for photo cross-linking by SurModics, Inc. Eden Prairie, MN or an organic photoreceptor material optimized for a wavelength from 300 nm to 2000 nm...".

To establish on the record that the process performed by Surmodics, Inc. is consonant to Appellant's rejected claims and disclosure and whether the process is, indeed, prior art to Appellant, Examiner provides, herewith, patents owned by Surmodics, Inc. that disclose modification of surfaces by affixing photoactivated crosslinkers. US Patent 6,077,698 (Swan et al.), US Patent Number 6,090,995 (Reich

et al.), and US Patent 6,465,178 (Chappa et al.) which are all owned by Surmodics, Inc. (assignee) and are all prior art references. In US Patent Number 6,077,698 assigned by Surmodics, Inc., Swan et al. discloses using linking agents to simultaneously immobilize or cross-link photoreactive molecules into a surface. Organic photoreceptor materials or photoreactive agents include anthraquinone, anthanthrone, and 4-bromomethylbenzophenone (dibromo anthanthrones) (see column 3, line 66 to column 7, line 3, column 5, line 21 to column 6, line 36, and Example 1). The surface is coated with a substance by forming an aqueous solution of the linking agent and the substance, placing the solution mixture in contact with the surface, and activating the photoreactive groups of the linking agent to cross-link the substance to the surface (see Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the immobilized reagents in the transparent cylinders taught by Anderson used in the apparatus of Nishina to include or otherwise substitute the photoreceptor materials, i.e. dibromo anthanthrone as disclosed by Surmodics, Inc., because SurModics specifically taught its application and suitability on surface of transparent cylinders for application in the device of Anderson. Further, the parameters set forth in claims 19 and 23 wherein "(the photoreceptor material) is activated by a wavelength of approximately 300 nm - 800 nm", constitute result effective variables which Surmodics, Inc. has shown may be obtained by optimization procedures. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 19 and 23 are for any particular purpose or solve any stated problem and the prior art teaches that photoreceptor materials often vary according to specific application or purpose or the sample being analyzed, the various detection materials and parametric requirements appear to work equally as well. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable range for dibromo anthranthrone as disclosed by the prior art by normal optimization procedures.

(10) Response to Argument

A) Appellant argues that Nishina does not disclose or suggest "determining a cytometric characteristic of a sample disposed in a transparent cylinder". Appellant specifically contends that Nishina does not teach every element contained in the claims because it fails to determine a cytometric characteristic of the liquid [from] within his extraction container.

In response, Nishina reads on the claimed invention, specifically claims 1 and 10 because both claims are not limited to *determining a cytometric characteristic from the sample which is contained and dispersed within the transparent cylinder* which is Appellant's invention as taught and encompassed within Appellant's disclosure and argued by Appellant throughout his responses. Indeed, Nishina teaches determining a cytometric characteristic of a sample disposed in a transparent cylinder as recited in claims 1 and 10 because it reads on determining cytometric characteristic information incorporated into a barcode label by virtue of detection of light signal by a determining means (sensor). Claims 1 and 10 which recite, *the "determining means" for determining at least one cytometric characteristic of a sample disposed in said transparent cylinder based on the light signal*, is implicitly deemed to correspond to different **sensors** which provide multi-parameter measurements such as CCD arrays, light scatter detectors, multicolor detectors, infrared detectors, photon counters, scintillation detectors, radioactivity detectors, confocal microscopy collection optics (see page 9, line 1 to page 10, line 1 and lines 25-30) as they can be used in determining at least one cytometric characteristic of a sample disposed in the transparent cylinder based on the light signal (cell phenotype, cell morphology). Since both the claims and the instant disclosure do not clearly link what specific structures are intended to encompass the "determining means" recited in claims 1 and 10, it is proper for purposes of *prima facie anticipatory or obviousness* rejection to interpret "determining means" for determining at least one characteristic of a sample disposed in said transparent cylinder based on light signal, to implicitly correspond to the "barcode reader" described in page 7, lines 11-15 (Example

7), which barcode readers are sensors which provide parametric measurements based on light signal consonant to those described in Example 15 used in determining at least one cytometric characteristic of a sample disposed in the transparent cylinder based on the light signal; because unpatented claims are given the broadest interpretation consistent with the specification.

B) Appellant argues that there is a distinction between reading a barcode affixed to a container and determining a cytometric characteristic of a sample disposed in a container because the act of reading the barcode (affixed outside the tube which is properly faced outward) is different from the act of determining cytometric characteristics of a sample in the tube, as claimed.

In response, the Office concurs that reading a barcode affixed to a container as taught by Nishina is distinct from *determining a cytometric characteristic from the sample which is contained and dispersed within the transparent cylinder*, which is language suggested to Appellant by the Office, and which is supported throughout Appellant's disclosure and arguments in the Appeal Brief. Indeed, reading a barcode label requires interrogation by light source and detection of signal from the outside of the transparent cylinder upon which label is affixed, whereas determining a cytometric characteristic from a sample within a container requires scanning the sample itself within the containment of the transparent cylinder. However, such teaching is not recited and delimited in the rejected claims. Indeed, Nishina teaches determining a cytometric characteristic of a sample disposed in a transparent cylinder as recited in

claims 1 and 10 because it reads on determining cytometric characteristic information incorporated into a barcode label by virtue of detection of light signal by a determining means (sensor). Claims 1 and 10 which recite, *the "determining means" for determining at least one cytometric characteristic of a sample disposed in said transparent cylinder based on the light signal*, is implicitly deemed to correspond to different **sensors** which provide multi-parameter measurements such as CCD arrays, light scatter detectors, multicolor detectors, infrared detectors, photon counters, scintillation detectors, radioactivity detectors, confocal microscopy collection optics (see page 9, line 1 to page 10, line 1 and lines 25-30) as they can be used in determining at least one cytometric characteristic of a sample disposed in the transparent cylinder based on the light signal (cell phenotype, cell morphology). Since both the claims and the instant disclosure do not clearly link what specific described structures are intended to encompass the "determining means" recited in claims 1 and 10, it is proper for purposes of *prima facie* anticipatory or obviousness rejection to interpret "determining means" for determining at least one characteristic of a sample disposed in said transparent cylinder based on light signal, to implicitly correspond to the "barcode reader" described in page 7, lines 11-15 (Example 7), which barcode readers are sensors which provide parametric measurements based on light signal consonant to those described in Example 15 used in determining at least one cytometric characteristic of a sample disposed in the transparent cylinder based on the light signal; because unpatented claims are given the broadest interpretation consistent with the specification.

C) Appellant argues that each claim rejected under 35 USC 103(a) depends from one of independent claims 1 and 10; as Appellant contends that claims 1 and 10 are patentable, all claims dependent therefrom are also rendered patentable over the cited prior art.

In response, all rejections under 35 USC 103 (a) have been maintained because the anticipation rejections made to independent claims 1 and 10 using Nishina as primary reference, have not been overcome and are being maintained.

(11) Related Proceedings Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

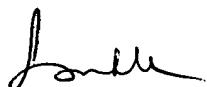
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